THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

INSTRUCTIONS FOR COMPLETION

CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.

NOTE: Laboratory directors performing nonwaived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be provided and submitted with the application. Information to be submitted with the application include:

- **Verification of State Licensure, as applicable**
- **Documentation of qualifications:**
  - **Education (copy of Diploma, transcript from accredited institution, CMEs),**
  - **Credentials, and**
  - **Laboratory experience.**

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.

I. GENERAL INFORMATION

For an initial applicant, check "initial application". For an initial survey or for a recertification, check "survey". For a request to change the type of certificate, check "Change in certificate type". For all other changes, including change in location, director, etc., check "other changes".

For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. Be specific when indicating the name of your facility, particularly when it is a component of a larger entity; e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. **NOTE: The information provided is what will appear on your certificate.**

Facility street address must be the actual physical location where testing is performed, including floor, suite and/or room, if applicable. **DO NOT USE A POST OFFICE BOX NUMBER OR A MAIL DROP ADDRESS FOR THE NUMBER AND STREET OF THE ADDRESS.** If the laboratory has a separate mailing address, please complete that section of the application.

NOTE: For Office Use Only—Date received is the date the form is received by the state agency or CMS regional office for processing.

II. TYPE OF CERTIFICATE REQUESTED

When completing this section, please remember that a facility holding a—

- **Certificate of Waiver** can only perform tests categorized as waived;*
- **Certificate for Provider Performed Microscopy Procedures** (PPM) can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;*
- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the laboratory is currently accredited by an approved accreditation organization.**

*A current list of waived and PPMP tests may be obtained from your State agency. Specific test system categorizations can also be reviewed via the Internet on *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm.*

**If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

III. TYPE OF LABORATORY

Select the type of laboratory designation that is most appropriate for your facility from the list provided. If you cannot find your designation within the list, contact your State agency for assistance.

IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format.

V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493.

VI. WAIVED TESTING

Indicate the estimated total annual tests volume for all waived tests performed.

VII. PPM TESTING

Indicate the estimated annual test volume for all PPM tests performed.

VIII. NON-WAIVED TESTING *(INCLUDING PPM)*

The total volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

IX. TYPE OF CONTROL

Select the type which most appropriately describes your facility.

X. DIRECTOR OF ADDITIONAL LABORATORIES

List all other facilities for which the director is responsible.

Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency.

TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALTIES

HISTOCOMPATABILITY
HLA Typing (disease associated antigens)

SYPHILIS SEROLOGY
RPR
FTA, MHATP

GENERAL IMMUNOLOGY
Mononucleosis Assays
Rheumatoid Arthritis
Febrile Agglutins
Cold Agglutinins
HIV
Antibody Assays (hepatitis, herpes, etc.)
ANA Assays

PARASITOLOGY
Direct Preps
Ova and Parasite Preps
Wet Preps

CHEMISTRY
Routine Chemistry
Albumin
Ammonia
Alk Phos
Bilirubin, Total
Bilirubin, direct
Calcium
Chloride
CO2, total
Ferritin
Glucose
Iron
Magnesium
pH
pO2
pCO2
PSA
Sodium
Vitamin B12
ALT/SGPT
AST/SGOT
Amylase
BUN
CK/CK isoenzymes
Cholesterol, total
Creatinine
Folate
HDL Cholesterol
LDH
LDH isoenzymes
Phosphorous
Potassium
Protein, total
GGT
Troponin
Triglycerides
Uric acid

Urinalysis
Automated urinalysis
Urinalysis with microscopic analysis
Urine specific gravity by refractometer
Urine specific gravity by urinometer
Urine protein by sulfasalicylic acid

BACTERIOLOGY
Gram Stains
Cultures
Sensitivities
Strep Screens
Antigen assays
(H. pylori, Chlamydia, etc.

MYCOBACTERIOLOGY
Acid Fast Smears
Mycobacterial Cultures
Mycobacterial Sensitivities

MYCOLOGY
Fungal Cultures
DTM
KOH Preps

VIROLOGY
RSV
HPV assays
Cell cultures

Endocrinology
TSH
Free T4
Total T4
Trilodothyronine (T3)
Serum-beta-HCG

Toxicology
Acetaminophen
Blood alcohol
Carbamazephine
Digoxin
Ethosuximide
Gentamycin
Lithium
Phenobarbitol
Phenytoin
Primidine
Procainamide
NAPA
Quinidine
Salicylates
Theophylline
Tobramycin
Valproic acid

HEMATOLOGY
WBC count
RBC count
Hemoglobin
Hematocrit (Other than spun micro)
Platelet count
Differential
Activated Clotting Time
Prothrombin time
Partial thromboplastin time
Fibrinogen
Reticulocyte count
Manual WBC by hemocytometer
Manual platelet by hemocytometer
Manual RBC by hemocytometer
Sperm count

RADIOBIOASSAY
Red cell volume
Schilling's test

IMMUNOHEMATOLOGY
ABO group
Rh(D) type
Antibody Screening
Antibody Identification
Compatability testing

PATHOLOGY
Dermatopathology
Oral pathology
PAP smear interpretations
Other cytology tests
Histopathology

CYTOGENETICS
Fragile X
Buccal smear

GUIDELINES FOR COUNTING TESTS FOR CLIA

For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch is counted as one test.

For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.

Testing for allergens should be counted as one test per individual allergen.

For **chemistry** profiles, each individual analyte is counted separately.

For **urinalysis**, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.

For **complete blood counts**, each **measured** individual analyte that is ordered **and reported** is counted separately. Differentials are counted as one test.

Do not count calculations (e. g., A/G ratio, MCH, and T7), quality control, quality assurance and proficiency testing assays).

For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.

For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.

For **cytology**, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.

For **cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.

For flow **cytometry** each measured individual analyte that is ordered and reported is counted separately.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

❑ Initial Application ❑ Survey ❑ Change in Certification Type ❑ Other Changes	CLIA Identification Number _____D_____ *(If an initial application leave blank, a number will be assigned)*
Facility Name	Federal Tax Identification Number Telephone No. *(Include area code)* Fax No. *(Include area code)*
Facility Address — ***Physical Location of Laboratory (Building, Floor, Suite if applicable.)*** *Fee Coupon/Certificate will be mailed to this Address unless mailing address is specified*	Mailing/Billing Address ***(If different from street address, include attention line and/or Building, Floor, Suite)***
Number, Street *(No P.O. Boxes)*	Number, Street
City State ZIP Code	City State ZIP Code
Name of Director *(Last, First, Middle Initial)*	For Office Use Only Date Received _____

II. TYPE OF CERTIFICATE REQUESTED *(Check one)*

❑ Certificate of Waiver *(Complete Sections I – VI and IX – X)*

❑ Certificate for Provider Performed Microscopy Procedures *(PPM) (Complete Sections I X)*

❑ Certificate of Compliance *(Complete Sections I X)*

❑ Certificate of Accreditation (Complete Sections I through X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes

❑ The Joint Commission ❑ AOA ❑ AABB
❑ CAP ❑ COLA ❑ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

- ❑ 01 Ambulance
- ❑ 02 Ambulatory Surgery Center
- ❑ 03 Ancillary Testing Site in Health Care Facility
- ❑ 04 Assisted Living Facility
- ❑ 05 Blood Bank
- ❑ 06 Community Clinic
- ❑ 07 Comp. Outpatient Rehab Facility
- ❑ 08 End Stage Renal Disease Dialysis Facility
- ❑ 09 Federally Qualified Health Center
- ❑ 10 Health Fair
- ❑ 11 Health Main. Organization
- ❑ 12 Home Health Agency
- ❑ 13 Hospice
- ❑ 14 Hospital
- ❑ 15 Independent
- ❑ 16 Industrial
- ❑ 17 Insurance
- ❑ 18 Intermediate Care Facility for Mentally Retarded
- ❑ 19 Mobile Laboratory
- ❑ 20 Pharmacy
- ❑ 21 Physician Office
- ❑ 22 Practitioner Other *(Specify)* _____
- ❑ 23 Prison
- ❑ 24 Public Health Laboratories
- ❑ 25 Rural Health Clinic
- ❑ 26 School/Student Health Service
- ❑ 27 Skilled Nursing Facility/ Nursing Facility
- ❑ 28 Tissue Bank/Repositories
- ❑ 29 Other *(Specify)* _____

IV. HOURS OF LABORATORY TESTING *(List times during which laboratory testing is performed in HH:MM format)*

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision)*

Are you applying for the multiple site exception?

❑ No. If no, go to section VI. ❑ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that has temporary testing sites?
❑ Yes ❑ No

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?
❑ Yes ❑ No

If yes, provide the number of sites under the certificate_____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?
❑ Yes ❑ No

If yes, provide the number of sites under this certificate_____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ❑ and attach the additional information using the same format.

NAME AND ADDRESS / LOCATION		TESTS PERFORMED / SPECIALTY / SUBSPECIALTY
Name of Laboratory or Hospital Department		
Address/Location *(Number, Street, Location if applicable)*		
City, State, ZIP Code	Telephone Number ( )	
Name of Laboratory or Hospital Department		
Address/Location *(Number, Street, Location if applicable)*		
City, State, ZIP Code	Telephone Number ( )	

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING

Indicate the estimated TOTAL ANNUAL TEST volume for all waived tests performed

❑ Check if no waived tests are performed.

VII. PPM TESTING

Indicate the estimated TOTAL ANNUAL TEST volume for all PPM tests performed _____

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the "total estimated test volume" in section VIII.

❑ Check if no PPM tests are performed

VIII. NONWAIVED TESTING *(Including PPM testing)*

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the information included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY		_____	**HEMATOLOGY**		
❑ Transplant	_____		❑ Hematology	_____	
❑ Nontransplant	_____				
			IMMUNOHEMATOLOGY		
MICROBIOLOGY		_____	❑ ABO Group & Rh Group	_____	
❑ Bacteriology	_____		❑ Antibody Detection (transfusion)	_____	
❑ Mycobacteriology	_____		❑ Antibody Detection (nontransfusion)	_____	
❑ Mycology	_____		❑ Antibody Identification	_____	
❑ Parasitology	_____		❑ Compatibility Testing	_____	
❑ Virology	_____				
DIAGNOSTIC IMMUNOLOGY		_____	**PATHOLOGY**		
❑ Syphilis Serology	_____		❑ Histopathology	_____	
❑ General Immunology	_____		❑ Oral Pathology	_____	
			❑ Cytology	_____	
CHEMISTRY		_____			
❑ Routine	_____		**RADIOBIOASSAY**		
❑ Urinalysis	_____		❑ Radiobioassay	_____	
❑ Endocrinology	_____				
❑ Toxicology	_____		**CLINICAL CYTOGENETICS**		
			❑ Clinical Cytogenetics	_____	

TOTAL ESTIMATED ANNUAL TEST VOLUME

IX. TYPE OF CONTROL

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT	
01 Religious Affiliation	04 Proprietary	05 City	08 Federal
02 Private		06 County	09 Other Government
03 Other _____ *(Specify)*		07 State	_____ *(Specify)*

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in ink)*	DATE

LABORATORY TEST LIST FOR WAIVED AND PPMP TESTING

Facility Name:	CLIA #
Name of Person Completing Form:	
Laboratory Director's Signature:	Date:

Please list the name of the waived test in the column on the left side and list the name of the corresponding kit and/or instrument and manufacturer in the column on the right side. **Ex- left column: whole blood glucose, right column: Bayer Diagnostics Elite Blood Glucose Meter and Test Strips.** If applicable, please check off the Provider Performed Microscopy Procedures performed.

ANALYTE / LABORATORY TEST	INSTRUMENT AND/OR KIT USED FOR TESTING

PROVIDER PERFORMED MICROSCOPY PROCEDURES	*EDUCATION
____ Wet Mounts; including vaginal, cervical or skin specimens	
____ All Potassium Hydroxide (KOH) preparations	
____ Pinworm Exams	
____ Fern Test	
____ Post-coital direct, qualitative exams of vaginal or cervical mucous	
____ Urinalysis; microscopic only	
____ Urinalysis; non-automated with microscopy	
____ Urinalysis; automated with microscopy	
____ Two or Three glass test	
____ Fecal leukocyte exam	
____ Semen Analysis; presence and/or motility of sperm	
____ Nasal Smears for Eosinophils	
* Education of all persons performing PPMP tests (i.e. MD, DO, PA, NP)	